User Manual

Introduction

Regulated Negative Pressure Wound Therapy (RNPT) has revolutionized and enhanced wound care during the last two decades. **Vcare α®** utilizes RNPT by multiple mechanisms of action, to remove fluids and infectious materials, help protect the wound environment, aid promote perfusion and provide moist healing environment, help draw together wound edges and promotes granulation.

RNPT is the controlled application of sub-atmospheric pressure to a wound using a therapy unit to intermittently or continuously apply negative pressure to a specialized wound dressing to help promote wound healing. The wound dressing is a resilient, open-cell polyurethane foam surface dressing and is sealed with an adhesive drape that contains the sub-atmospheric pressure at the wound site. Important safety features enhances patient safety by regulating pressure at the wound site and warning possibility of uncontrolled bleeding. Additionally, **the Vcare α®** helps direct drainage to a specially designed canister that reduces the risk of exposure to exudates, fluids and infectious materials

Intended Use

The Vcare α® is indicated for wound management via application of a pre-set level of continuous or intermittent negative pressure to the wound for removal of fluids, including wound exudates, irrigation fluids, and infectious materials. It is intended for management of chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns, ulcers (i.e., diabetic or pressure), flaps and grafts.

This user manual includes important information and instructions for correct and safe operation of the Vcare α® device. It is provided for training of personnel and as a reference for users.

Caution: When applying Vcare α® wound treatment products, be sure to apply the product according to manufacturer's instructions for use.

Caution: Not for use among children below the age of 6. Before using consult with licensed and specifically trained physician.

Important Safety Warnings

Pay special attention when treatment is applied for elderly and young patient with sensitive for highly delicate skin. The care provider should have a vast establish experience with vacuum treatment in order to define the vacuum that should be applied, the mode of operation and the duration of exposure to treatment.

In order to reduce potential risk for serious or fatal injury, prior to use read and follow the instructions for use. This user manual is part of the Vcare α® system. All safety information and warnings must be read prior to use.

The Vcare α ® is intended to be operated by licensed and specifically trained medical staff. Treatment mode and parameters must be set only by physicians or dedicatedly trained nurses.

Important

Do not use the Vcare α® system without consulting and supervision of a physician. Read through and follow the user instructions and safety information before using the Vcare α® system. Using the system without physician supervision or without following the clinical guidelines on this manual may risk the patient and may result in serious injury.

For safe and proper operation of the Vcare α® system, the safeguards below must be followed:

- The operation of this product must be according to this manual.
- No modification of the Vcare α® system is allowed without prior authorization of IVT Medical Ltd.
- If this equipment is modified, appropriate inspection and testing must be conducted by IVT Medical Ltd. service personnel to ensure continued safe use of equipment.
- Assembly, adjustments, modifications, maintenance and/or repair of the Vcare α® system must be carried out by a qualified personnel authorized by IVT Medical Ltd.

- To avoid risk of electric shock, the Vcare α® unit must only be connected to a supply main with protective earth.
- Do not connect this product to damaged external power supply.
- Do not insert any object into any opening or tubing of the Vcare α® unit.
- The Vcare α® disposables are intended to be used only with the Vcare α® unit.
- Do not shake or rock the Vcare α® unit.
- The Vcare α® unit should not be placed over heated surfaces.
- Special precautions regarding EMC must be taken when installing and preparing the Vcare α® unit for operation according to the EMC section in this manual.
- Portable and mobile RF communication equipments may produce Electromagnetic interference. If interference is suspected, separate the equipment and contact your service provider. For further details, see EMC section in this manual.
- Do not touch the external fuse or fuse holder and the patient simultaneously.
- Do not spill any fluids on the Vcare α® unit or any of its parts.
- If any liquid is spilled on the system, disconnect the unit from its external power adapter and wipe using an absorbent cloth. Before reconnecting the unit, make sure that the power connector is dry. If the Vcare α® is not working properly, contact IVT Medical or local authorized distributer.

Disposal

- The Vcare α® unit must be returned to IVT Medical at the end of its operational life, i.e. following 5,000 hours of the internal pump operation.
- All disposables (Vcare α® wound dressing, drapes, collection canister, tubing, connectors and filters) should be handled and discarded according to institutional procedures and local, state and federal regulations.
- If not disposed properly, contact with the disposables may lead to contamination or super infection.

Safety Information

Disposables

The disposables of the Vcare α® system are intended for single use only.

Do not re-use or re-sterile the disposables as this may cause infection to the wound.

Warning: Do not use non-sterile disposables.

Always dispose the wound dressing, collection canister, drapes and tubing according to hospital and bio-hazard protocols and according to institutional procedures and local, state and federal environmental regulations.

Indications for use of Vcare α® system

The Vcare α® system is indicated for wound management via application of a pre-set level of continuous or intermittent negative pressure. The Vcare α® system may promote wound healing by either removal of excess exudate or irrigation fluids and infectious materials. It is intended for management of chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns, ulcers (i.e., diabetic or pressure), flaps and grafts.

Specifically, the Vcare α® system is indicated to be used with the following wounds:

- Chronic wounds
  - Wounds in diabetic and PVD-affected limbs
  - Decubitus ulcers
  - Trophic ulcers
  - Venostatic, arterial, diabetic, neuropathic, post irradiation, and pressure sores
- Dehisced and infected surgical wounds and complications of failed sternal closures
- Traumatic Wounds
- Deep and partial-thickness small-to-medium size burns
- Treatment of skin grafts and flaps
- Extensive tissue losses
- Treatment of open fractures
- Crush injuries
- Compartment syndromes

Contraindications

Vcare α® system is contraindicated in case of:

- Uncontrolled bleeding.
  - Following trauma
  - Following surgery
  - Patients with hematological disorders
  - Vcare α® system should be restricted in patients with open wounds who are treated with anticoagulants or suffer hematological disorders.
- A meticulous homeostasis should be established prior to the application of Vcare α® system. The care provider should ensure that no exposed blood vessels, nerves, areas with fresh vascular anastomosis and internal organs are in direct contact with the vacuum system.
- Ulcerated malignant wounds are contraindicated for treatment by Vcare α® system as vacuum treatment may accelerate tumor growth within the wound cavity (with exception of palliative care to enhance quality of life).
  Note: Treatment of long standing unhealed wounds should be evaluated for possible malignancy (by biopsy of ulcers) prior to RNPT.
- Vcare α® system is contraindicated for treatment of non-enteric unexplored fistulas. Exploration of a fistula and determinations of its extensions and content should precede Vcare α® application.
- The use of Vcare α® system is contraindicated in apparent anaerobic infection.
- Vcare α® system is restricted to small and medium size burns, as treatment of wide partial-thickness and deep burns may lead to extensive extra-cellular fluid loss and electrolyte imbalance by the applied suction.

Vcare α® system may be ineffective or contraindicated in case of:

- Necrotic tissue with eschar
- Areas where adhesive tape application is limited (dense hairy areas, mucus membranes, and joints that cannot be fixated).

General Guidelines

- Always use the lowest effective negative pressure.
- Safety measures regarding the use of Vcare α® system should always be considered and implemented.
- Conservatively debride necrotic tissue prior to the use of vacuum treatment with the Vcare α® system.
- Evaluate the need for initiation and cessation of systemic antibiotic treatment in conjunction with the Vcare α® system.
- Vacuum levels in Vcare α® system should be tailored to each specific wound and adjusted according to patient's clinical condition. General guidelines and recommended vacuum levels are shown in the table below.
- Inexperienced personnel is advised to always use the cyclic-continuous mode or consult a trained physician regarding the treatment settings before using the Vcare α® system.
- When applying external vacuum - make sure that the vacuum level supplied from the external vacuum source is 50 mmHg above the desired working pressure but should not exceed 200 mmHg.
- It is recommended to connect the unit to an external vacuum source by a pressure regulator.
- The external vacuum tube must be disconnected from the unit when external vacuum is not in use.
- When working with the unit's internal pump, make sure that the external vacuum tube is not connected to the unit.
- The device must be operated in a quite environment with background noise of no more than 45-50dB
- A portable modality of utilization enables via a mobile stand.
- IV (intravenous) medication administration by IV pump can be integrated with Vcare α® treatment. The pump shall be hanged on IV pole that structured in the mobile stand or being placed on a flat surface that is higher than the Vcare α® unit.

Warnings regarding clinical application of the Vcare α® system

- Bleeding and infection should be anticipated during the use of RNPT.

- When bleeding risk is anticipated to be high (early following trauma or surgery), working negative pressure levels should be set as low as possible and should not exceed a maximum of 80 mmHg.
- While working on stiff surfaces, as in clinical cases of low- perfused tissues like PVD, diabetic, traumatic wounds, low vacuum is essential in order to prevent tissue ischemia.
- Maximal Flow Rate Setting: Maximal flow rate from the wound through the tubing to the collection canister is pre-set as default to be up to 100 ml/hr. In case that the flow exceeds this limit, an alarm is activated and the suction apparatus shuts down. It is obligatory to maintain this default setting. Increasing the maximal flow rate allowed from the wound may eliminate control of acute bleeding.
- Alarms Setting: Alarms are pre-set as default to audio & visual alarms. Any alarm condition will be indicated by audio (a repetitive beeping sound) and visual (A flickering triangle symbol in the middle of the display screen and an indication LED) alarms. Changing this pre-setting should be considered carefully. Change of alarms settings may prevent from the care-giver the detection of critical indications regarding the vacuum treatment.
- Never leave a wound covered for an extended time without effective negative pressure. As the Vcare α® system is operating, fluids are discharged and constantly evacuates from the wound. Once the vacuum is halted, the system is at risk of becoming occlusive, which might lead to infection.
- Wound dressing must be replaced according to the clinical guidelines or physician's judgment in order to prevent super infection to the wound.
- Constant efficient negative pressure should be applied to the wound in order to avoid bacterial overgrowth and super-infection. If vacuum is ineffective for over 30 min, aeration of the wound by removal of occlusive dressing or other form of ventilation should be considered.
- The Vcare α® system should not be used in cases with apparent or suspected anaerobic infection.
- Negative pressure may exacerbate uncontrolled bleeding. All precautions should be taken in order to avoid uncontrolled bleeding and the **immediate cessation of RNPT in case of excessive bleeding should be executed.**
- Avoid high negative pressure during the early stage of trauma treatment.

- Severe, life-threatening bleeding may result from the application of vacuum in treatment of acute trauma, immediately after surgery, at early stages following debridement of wounds, in patients treated with anticoagulants or suffering from hematological disorders.
- Setting high values of negative pressures may induce ischemia and may aggravate clinical ischemic conditions such as in peripheral vascular disease, diabetic leg, and traumatized tissue.
- Excessive topical pressure may lead to compromised blood circulation and impairment of wound healing.
- Treatment of long standing unhealed wounds should be evaluated for possible malignancy by biopsy of ulcers.
- Treatment of Diabetic Foot
  Diabetic foot patients with an ankle-brachial ratio less than 0.5 should be treated with the lowest effective negative pressure and should be closely monitored for distal perfusion impairment, mainly when having circumferential vacuum wound dressing.
- Treatment of Contaminated Wounds
  High levels of negative pressure (deeper vacuum) may be needed for the initial treatment of heavily contaminated wounds.
- Treatment of Tissue Ischemia
  Tissue ischemia can be managed and avoided by short term higher negative pressure values applied in an intermittent mode.
- Dot not place the mold or apply vacuum over a healthy tissue. Applying vacuum on healthy tissue may cause irritation and damage the skin.

Clinical Guidelines of the Vcare α® system

The clinically based range of recommended vacuum pressure, level range, span, frequency of operation, mode and exchange of dressing in Vcare α® system for various conditions is presented in the following table. The practicing physician should recognize the need for specific settings for vacuum work/pause ratio, and the frequency of dressing changes adjusted to the varying clinical conditions for each individual wound.

Guidelines for clinical application of Vcare α® system

The presented guidelines should be regarded as general recommendations

Intended use – type of wound	Pressure range (mmHg)	Operation mode frequency range (on/off min)	Rate of Dressing change (every- x days)	Remarks*
Trauma				
Acute infection	40-120	2-2- 3/1	1-3	Stop active bleeding before starting vacuum treatment. Watch for active bleeding. Do not apply on blood vessels or internal organs. Apply lowest pressure possible in range. Increase pressure and frequency of dressing change for treatment of infected traumatic wounds. Apply non-adhesive antimicrobial dressing to the wound below the sponge. Intermittent mode is preferable.
Chronic	40-80	2-5/1-2	2-4	
Chronic Wounds- Decubitus ulcers				
Acute infection	40-120	2-2- 3/1	1-3	Conservatively debride necrotic tissue prior to application of Vcare α® system. Start treatment with greater vacuum in intermittent mode when wounds are heavily infected. Reduce pressure as the wound becomes cleaner. Consider combined systemic antibiotic treatment.
Chronic	40-80	2-5/1-2	2-4	
Peripheral Vascular disease- Diabetic Foot				
Acute infection	60–120 (intermittent use only!)	2-3/1-2	1-2	Correlate vacuum treatment with measured Ankle-brachial pressure ratio. Use lowest pressure possible in range. Extremely greater negative pressure (140–100 mmHg) may be applied for a few days for treating heavily infected wounds, applying a 2/1 ratio of intermittent mode and frequent dressing changes. Reduce pressure as soon as the wound becomes cleaner. Evaluate distal perfusion.
Chronic	60–80	2-5/1-2	5-2	
Burns				
Acute	60–80	3–5/1–2	1-3	Limit application to small to medium sized deep burns. Restrict surface area to be treated according to the amount of fluid discharge from the wound. Stop treatment If excessive fluid is drained. Watch for acute bleeding. Determine and correct electrolyte imbalance, evaluate need for replacement therapy and systemic antibiotic treatment. Conservatively debride eschar.
Sub acute	60-120	3–5/1–2	1-3	
Infected burn	60-140	2-5/1-2	1-2	
Skin Graft				

only! The treating physician should amend and adjust treatment to each individual clinical condition.

Skin Graft	50–80	Continuous for 3–4 days followed by intermittent mode 6–4/1–2	4-7	Stop active bleeding before starting treatment. Use lowest pressure possible in range. Apply non- adherent, antimicrobial dressing (spacer) to cover the skin graft below sponge. Mesh skin graft

The above guidelines should be regarded as general recommendations only! The treating physician should amend and adjust treatment to each individual clinical condition.

Vcare α® Unit Components

Vcare α® Unit

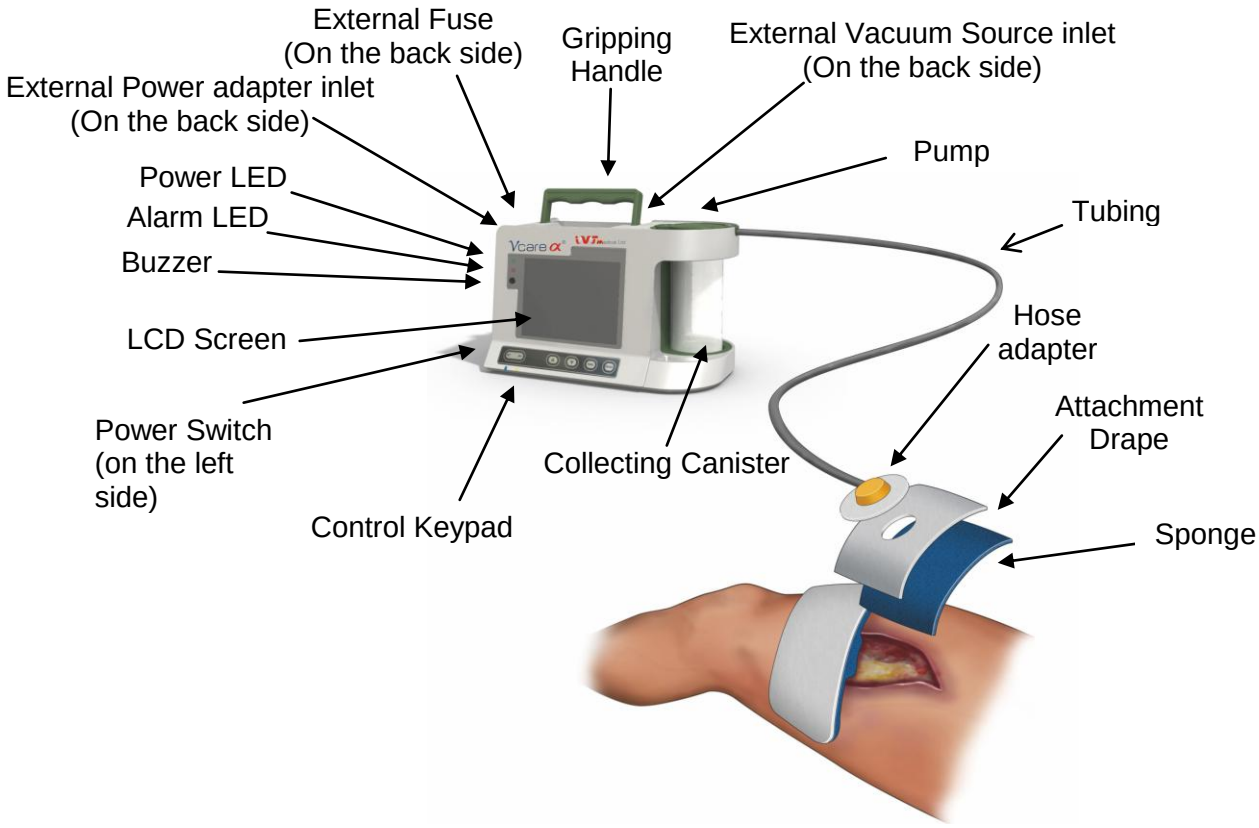
Unit Main Components

- Internal Suction Pump
- Display Screen and Controls
- Internal Battery

Disposables

- A Disposable Wound dressing Kit – includes:
  - Wound Dressing Sponge.
  - Drape Stripes.
  - Distal Connecting Tube and Irrigation Port– connecting between the attachment drape and the canister proximal tube.
- Canister Proximal Tube - connecting between the distal connecting tube and the collection canister.
- Wound Discharge Collection Canister – includes means of protection and control.

The following image illustrates the Vcare α® system



Vcare α® Device Technical Operation

Introduction

Vcare α® System Components and Functions

1. Vcare α® Unit

1.1. Main Power Switch – turn the Vcare α® on/off (0/1).

1.2. An Internal Software-controlled Suction Pump

1.3. Control Panel

On the bottom of the Vcare α® unit there is a control panel that includes six buttons for controlling the software and adjusting the device and treatment settings:

EXT	INT	↑	↓	FUNC	OP/SET

1.3.1. EXT – defines the vacuum source to be external.

1.3.2. INT – defines the vacuum source to be the internal pump.

1.3.3. FUNC – this button has the following functions:

- Long press in Menu Selection Screen: entering System Set-Up Menus screen.
- Short press while setting parameters in treatment menu– displays the value of the current function in [a] (primary numerical display) and allows manual setting of the value.
- Long press while setting parameters in treatment menu– switches to System Set-Up Menu screen.
- Short press in Stand-by mode: entering Treatment menu.
- Short press while vacuum is operating: displays treatment settings on the screen (Work/Pause time, Upper/Lower limit and Max. Flow).

1.3.4. OP/SET – this button has the following functions:

- Set a flickering value: While browsing throughout the menus, the default value of each function is flickering on the screen. By pressing OP/SET, the user sets the flickering value. This will cause the value to stop flickering.
- When the Stand-by screen is displayed, pressing the OP/SET button will start or stop the vacuum operation.
- The user can than choose to start working (go to the main screen) by pressing shortly on the OP/SET button.

1.3.5. ↑ up scroll arrow

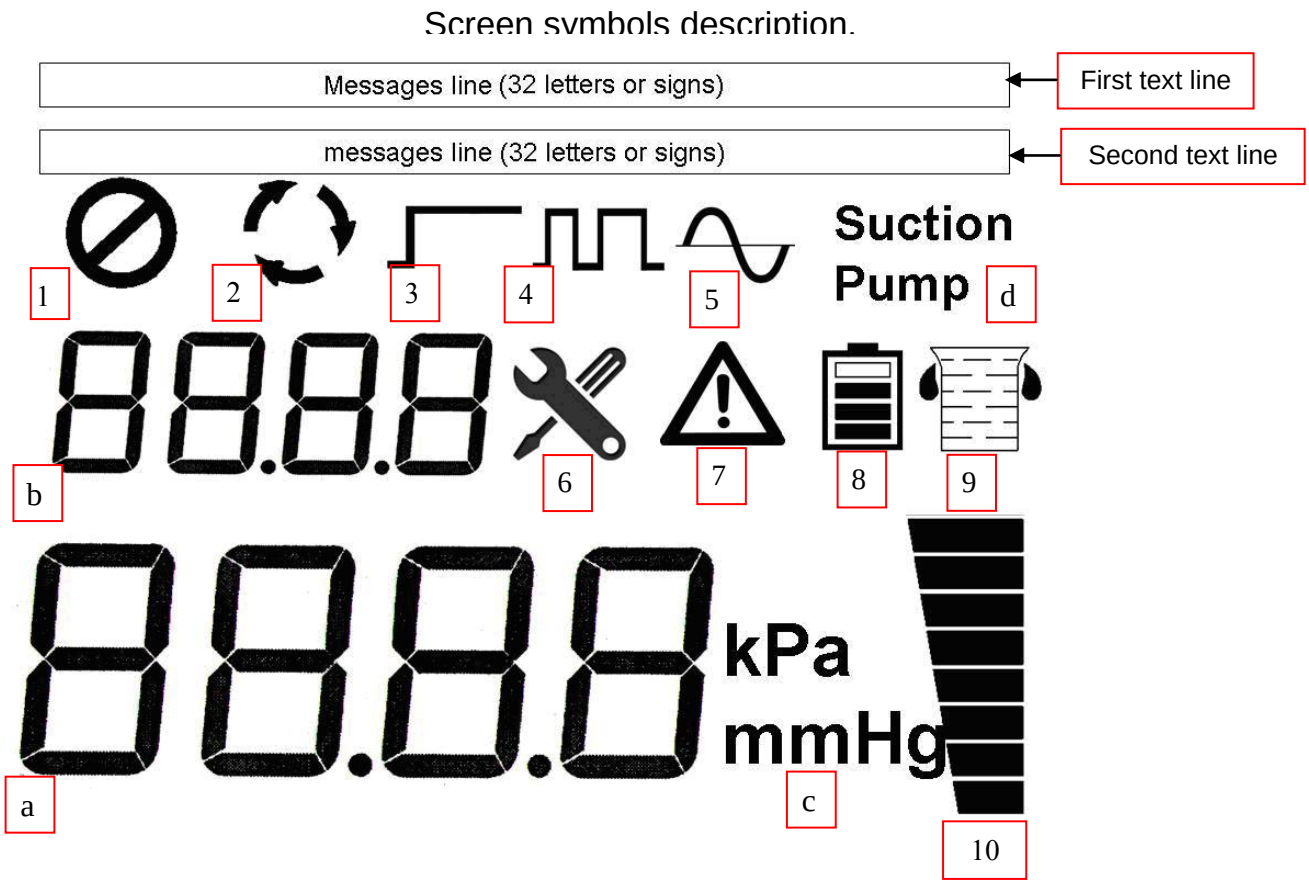
1.3.6. ↓ down scroll arrow

The scroll arrows are used in the menus and have the following functions:

- When a function value is flickering, the user can use the arrows to switch between values. Long press on the arrow buttons will faster the scrolling of the available values.
- When a function value is not flickering the user can use the arrows to switch between functions (go up and down in the menu).

1.4. LCD Screen Display

Displays information and messages regarding working mode, settings, alarm, current pressure, liquid level scale, suction and power source (internal or external). The following figure illustrates the screen display with all symbols:



Symbol	Symbol Number	Description
	1	Standby – displayed when no vacuum operation mode is applied. Flickering when vacuum is paused (in intermittent mode).
	2	Work Status – displayed when one of the vacuum operation modes is operating: cyclic-continuous, intermittent or continuous.

	3	Continuous Operation Status – displayed when continuous vacuum is applied.
	4	Intermittent Operation Status – displayed when intermittent vacuum is applied.
	5	Cyclic-Continuous Operation Status – displayed when cyclic-continuous vacuum is applied.
	6	Setting Mode – displayed when setting the treatment parameters in Treatment, System Set-Up menu.
	7	General Warning Status – displayed when one of the alarms or alerts is activated.
	8	Battery Status – displayed when the device is not connected to a power source. This symbol indicates the battery voltage: 4 bars indicate full battery – 12.2V or more, 3 bars: 12.2V – 11.8V, 2 bars: 11.8V– 11.37V, 1 bar: 11.37-10.96V, 0 bars: 10.96 – 10.8.
	9	Full Canister Status – displayed when the canister is full and must be replaced.
	10	Canister Fill Status – indicates the canister fill level. Flickering (eight full bars) when high flow alarm is set.
	a	Primary numerical display: In Set-Up menu- displays the adjustable value of the current function. During vacuum operation- displays the actual pressure applied by the system.
	b	Secondary numerical display: displays the pre-set Working Negative Pressure selected by the user during vacuum operation.
kPa mmHg	c	Vacuum units - displays the units of applied vacuum.
Suction Pump	d	Vacuum source- indicates the applied vacuum source. Suction indicates External vacuum, Pump indicates internal pump.

	Alarm symbol 1	General alarm signal: indicates that an alarm condition is present.
	Alarm symbol 2	Audio off signal: indicates that the auditory alarm signal is off (when the user chooses only visual alarm).

1.5. Indication LEDs

1.5.1. Power LED- green LED

1.5.2. Alarm LED- red/ yellow LED

1.6. Canister Socket

1.6.1. Flow PCB

1.6.2. Canister Release Button

1.6.3. Phototube Holder

1.7. Electric Outlet

1.8. External Vacuum Source Inlet

1.9. External Fuse

1.10. Integrated Battery

Integrated charger provides up to 1 hour of operation battery life.

An automatic charging facility switches to battery power when main power is off.

The Vcare α® unit shall be connected to an approved medical grade AC/DC adapter (UL, TUV or CSA certification is required).

Note: When connected to the external power adapter, the Vcare α® apparatus is considered as ME SYSTEM (refer to IEC 60601-1).

The power adapter must comply with the specifications described below in the specifications section. However, the unit can also operate using its internal rechargeable battery when not connected to the power supply. It is advised to connect the unit to the main power supply through the power adapter whenever possible in order to keep long battery life and to keep the battery fully charged.

 Warning: the external power adapter must comply with the specifications listed in the specifications chapter in this manual.

1.11. A Gripping Handle.

1.12. External vacuum source tube.

2. Disposables

2.1. A wound discharge Collection Canister

2.2. Tubing

2.2.1. Distal Connecting Tube, a tube adapter attached to its distal end and an Attachment drape.

2.2.2. Canister Proximal Tube.

2.3. Sponge-The Sponge consists of a basal porous layer and a covering air-tight layer (drape).

2.4. Drape Stripes.

Note: all items in the Vcare α® system are suitable for use within the patient environment.

Vacuum Operation Modes

The Vcare α® system can be used to apply negative pressure in the following modes:

1. Cyclic-Continuous mode – basic mode of operation. The neg. pressure oscillates around a pre-determined value to a range of ± 20% of the baseline neg. pressure.
2. Intermittent mode – advanced mode of operation, allows setting and adjusting different system parameters. When using this mode of operation, it is highly recommended to follow the clinical guidelines for recommended vacuum pressures and wound dressing changes provided earlier in this manual.
3. Continuous mode - advanced mode of operation, allows setting and adjusting different system parameters. Typically used following skin transplant applications. When using this mode of operation, it is highly recommended to follow the clinical guidelines for recommended vacuum pressures and wound dressing changes provided earlier in this manual.

Primary Unit Functions Setting

Positioning of the Vcare α® Unit

The Vcare α® unit should be placed close to the patient bed, in proximity to the external vacuum and electricity sources. The unit should be preferably operated by direct connection to a grounded electrical source and external vacuum source. The unit can be placed on a stable flat dry surface or can be attached and secured to a designated mobile stand to enable patient ambulation.
The device must be operated in a quite environment with background noise of no more than 45-50dB.

- Make sure that the external power adapter and its connecting cables are not creating a tripping hazard.
- Make sure that the ventilation holes at the back of the unit are not covered or blocked.
- If the device is connected to mobile stand there is a need to make sure that it is securely connected to the mobile stand and that the lock-pin is closed.

The Vcare α® unit and tubing should be placed in a visible location in order to enable direct eye contact with the system and enable early detection of bleeding and/ or effective vacuum application to the treated area.

Collection Canister Installation

1. Insert the collection canister into the canister socket in the Vcare α® unit by pressing it inwards. When properly inserted, a clicking sound is heard. Make sure that the canister is placed secured and sealed in the canister socket for effective operation of the vacuum.
2. Connect the canister proximal tube to the canister tubing outlet.

Replacing the Collection Canister

The collection canister may be replaced during normal operation, alarm condition or routine maintenance.
The canister must be replaced when the liquid level exceeds 650 ml. In this case, an alarm will be activated. The vacuum operation will stop when the fluids level in the Canister reaches 700 ml.

When fluids in the canister reach approximately 650 ml, solidification process of the fluids by the hydro-gel at the top of the canister will start, and will be completed within 60 minutes.

 Warning: The collection canister and tubing are intended for single use only and must be disposed off after usage according to hospital and bio-hazard protocols and according to institutional procedures and local, state and federal environmental regulations.

Once the fluids have solidified and reached 650 ml, follow the steps below to replace the canister:

1. Turn off the device using the main power switch.
2. Disconnect the proximal tube from the distal tube.
3. Press the canister release button, hold the canister gently and pull it upwards in order to take it off its socket.
4. Seal the canister through the proximal connecting tube using the tube lid.
5. Discard the canister and tubing according to the hospital and bio-hazard protocols.

Insert a new collection canister to the socket. A clicking sound will indicate that the canister is properly inserted.

6. Connect the new canister proximal tube to the distal tube connected to the dressing.
7. Turn the device on using the main power switch.
8. Activate Vacuum using the OP/SET button.
9. Verify that the applied pressure displayed on the screen matches your pre-defined setting.

Setup for Wound Dressing Application

1. Perform adequate conservative debridement of the wound to minimize bleeding prior to dressing application.
2. Make sure that the wound area is clean.

- It is possible to apply spacer in the interface between the sponge and the wound. The spacer should serve specific conditions in RNPT treatment. To prevent adherent of the sponge to the underlying tissue (or skin graft), a non-adherent

gauze should be used. Wound irrigation may be applied to the wound if necessary. Irrigation system is not part of the Vcare α® system.

 Warning: Do not place the sponge or apply vacuum over a healthy tissue. Applying vacuum on healthy tissue may cause irritation and damage the skin.

 Warning: Avoid cutting the dressing directly over the wound in order to prevent particles from entering the wound bed.

3. Choose a suitable sponge according to the wound dimensions.
4. Choose drape stripes in a suitable length for a safe attachment of the Sponge to the surrounding skin (the length should be determined in compliance with the Sponge size).
5. Dry the wound edges for better sponge and drape stripes attachment.
6. Remove the taping from the drape stripes and use them to attach the sponge edges to the wound surrounding tissue. It is recommended to cover 3-5 cm of surrounding intact skin. Make sure that the drawing on the top of the drape is visualized (visual regulation).
7. Choose the location to apply the distal tube and attachment drape. The location should be at the most dependent area of the wound to prevent from accumulation of fluids in the wound bed.
8. At this location, cut a hole through the covering layer of the sponge (the drape layer), approximately 1-2 cm in diameter, leaving the foam layer of the mold mostly intact. Make sure that the size of the hole is sufficient to allow fluid passage through the drape. It is very important to cut a complete hole (rather than a slit), since a slit may not allow fluid passage through the drape.
9. Remove the taping from the end of the distal tube and attach it to the sponge above the hole.
10. Connect the distal tube to the canister proximal tube via the two way tube connector.

Wound Dressing Removal

 Warning: The wound dressing sponge, proximal and distal connecting tubes and attachment drape are intended for single use only and must be disposed off after usage

according to hospital and bio-hazard protocols and according to institutional procedures and local, state and federal environmental regulations.

1. Turn the vacuum operation off using the OP/SET button in the control panel.
2. Turn the Vcare α® system off using the power switch.
3. Disconnect the distal tube from the proximal tube.
4. Remove the drape stripes from the surrounding of the wound.
5. Remove the sponge from the wound bed.
6. Make sure that the entire sponge has been removed.

Positioning of the Vcare α® Unit on the Mobile Stand

1. Hold the Vcare α® with one hand by its carrying handle when its LCD screen faced toward the front of the mobile stand.
2. Slide the Vcare α® by its external plate on the shelf track that placed on the upper side of the mobile stand.
3. Pull the pin-lock until the external plate is properly inserted into the shelf track.
4. In order to complete its positioning, release the pin lock and continue sliding the external plate until the external plate is locked by the pin lock (a clicking sound needed to be heard).

Vcare α® Termination of Operation

1. Turn the vacuum operation off using the OP/SET button in the control panel.
2. Turn the Vcare α® system off using the power switch.

Vcare α® Operation

Before operating the Vcare α®, verify that:

- The Vcare α® is placed on a suitable surface according to Positioning the Vcare α® unit section in this manual.
- The collection canister is properly installed according to Disposable canister installation section in this manual.
- The wound dressing is properly applied according to Setup for wound dressing application section in this manual.

- When connecting the Vcare α® to its mobile stand make sure it is properly connected according a clicking sound is heard.

1. Use a suitable external power adapter to connect the Vcare α® unit (via the electric receptacle) to the wall electrical outlet.

When connecting the unit to the external power adapter, the operator should be facing the back of the device, in front of the power electrical outlet.

 Warning: The External power adapter must follow the specifications detailed in the External power adapter specifications section in this manual.

 Warning: Do not connect the unit to a damaged external power adapter.

Note: In order to work in Battery mode, make sure that power adapter is not connected.

 Warning: The internal battery is not accessible for users. In case that battery malfunction is suspected during warrantee period, contact IVT Medical Ltd.

The Power indication LED is lit.

2. Turn the Vcare α® unit on using its power switch button located on the left side of the unit.
   - When turning the device on, the operator should face the power switch on the left side of the device.
   - During treatment parameter settings and vacuum operation, the operator should face the front side of the Vcare α® unit (in front of the screen and control panel).

3. Main screens

3.1. Opening Screen

As the unit is turned on, an opening screen is displayed for approximately 10 seconds. The first line displays the caption *IVT Medical Ltd.* and the second line displays *Vcare Alpha*.

3.2. Self test screen

Following the Opening screen, the LCD screen is being self-tested for a few seconds (this self-test is performed every time the unit is turned on). During the self-testing phase, the display shows "TEST LCD", symbols 1-10 are displayed on the

screen, digits in [a] and [b] vary from 0 through 9, bars in symbol no. 10 fill gradually and the buzzer produces a short beeping sound.

3.3. Menu selection screen

After the LCD self test screen is displayed, the user will have two options for setting the treatment's parameters: pressing ↓ for treatment menu, in which basic treatment parameters are set, or pressing FUNC for approximately 5 seconds in order to enter the advanced set-up menu (for detailed information about the menus, go to the menus chapter).

3.4. Stand-by screen

This screen is displayed after setting the treatment parameters and before starting the vacuum operation. The caption *Stand-by* is displayed in the first line. Pre-set neg. working pressure is displayed in [b], pressure units are displayed in [c], vacuum source is displayed in [d], and symbol no. 1 is displayed on the screen. The user is instructed to press OP/SET to start the vacuum operation.

3.5. Working mode screen

As the user starts the vacuum operation, the working mode screen is displayed during treatment. The working mode screen displays the pre-set working neg. pressure in [b], the actual pressure applied to the wound in [a], the pressure units in [c], the vacuum source in [d], along with symbol no. 2.

As the vacuum pauses when working in intermittent or cyclic-continuous mode, symbol no. 1 is flickering on the screen as an indication.

4. Vacuum Applying Mode Determination

The button INT/EXT allows the user to choose the desired vacuum source:

4.1. Internal Suction Mode (Pump)

In order to work with the device's internal suction apparatus press INT button.

4.2. External Suction Mode

Press EXT button in order to work with external vacuum source. This requires connection to the external source using the external vacuum source tube.

For continuous mode of operation use an external vacuum source. The device cannot operate in continuous mode (and will not allow choosing 0 minutes pause time) when operating under internal suction mode.

For cyclic-continuous mode, it is recommended to use external vacuum source. When using the internal pump in cyclic continuous mode, the pump will pause for 1 minute every 10 minutes of operation. All other settings will operate in the same way for both external and internal suction modes.

5. Menus

5.1. Treatment Setting Menu

When entering the treatment setting menu, the following screen is displayed:

In menu selection screen, press ↓ in order to enter Treatment Setting Mode (in order to change system parameters, press FUNC for approximately 5 seconds and see the Set-Up Menu section for guidelines).

While setting treatment parameters, symbol no. 6 appears on the screen as an indication.

Using the control panel in treatment setting mode:

While browsing through the treatment setting mode, default values of the treatment parameters will flicker in the first text line. The other displayed values are recommended treatment values (except for the risk of bleeding parameter). The second line displays guiding messages to help the user in choosing the appropriate treatment settings.

At any stage of treatment setting, when a flickering value is displayed, press the control panel OP/SET button shortly to select the displayed value for the current treatment parameter, or use the up and down scroll arrow buttons to scroll between

available values for the current parameter and then press OP/SET to select the required value.

After pressing OP/SET, the displayed value will stop flickering.

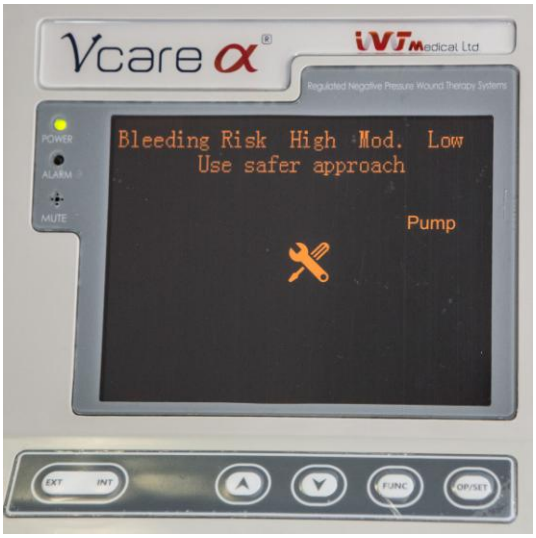
When the value is not flickering, use the up and down scroll arrow buttons to scroll between treatment parameters.

At certain treatment setting functions, pressing FUNC shortly allows advanced treatment settings. In this mode, the default value is displayed in [a], and by using the up and down scroll arrow buttons the value can be changed in a pre-set range.

At any stage of the treatment setting mode, holding the FUNC button for approximately 5 seconds allows switching to Set-Up Menu.

5.1.1. Risk of Bleeding Evaluation

When entering the risk of bleeding menu, the following screen is displayed:



The default risk of bleeding value is flickering.

This function determines the evaluated risk of bleeding from the wound. The following risk evaluations are available: High, Moderate or Low risk of bleeding. As a default, for the safety of the patient, the risk is pre-set to be High. For each option, the working neg. pressure will be limited as follows:

Risk of Bleeding / Working Neg. Pressure [mmHg]	High	Moderate	Low
Intermittent Operation Mode	30-65	30-90	30-200

Cyclic-Cont. Operation Mode	40 / 50	40 / 50 / 75	40 / 50 / 75 / 100 / 125

As the Risk of Bleeding is set to High or Moderate, for the safety of the treatment, Max Flow and Alarms will be limited to the default values of 100 ml/hr and Audio & Visual, respectively.

Use the up and down scroll arrow buttons in the control panel to change the flickering value and determine the evaluated Risk of Bleeding.

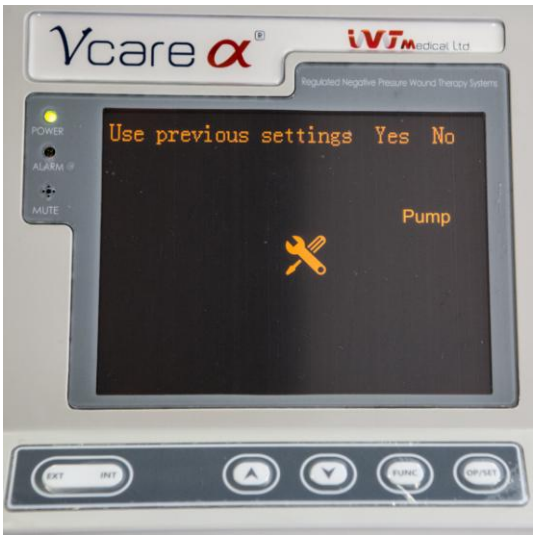
Press the OP/SET button to finalize your selection. The value stops flickering.

Press ↓ to continue to the next parameter.

⚠ Warning: Consider carefully any change from the default settings.

5.1.2. Use Previous Settings

When entering Use Previous Settings menu, the following screen is displayed:



The user may choose to use the previous treatment settings if the Risk of Bleeding is identical to that of the previous treatment. The default value of this function is NO.

Use the up and down scroll arrow buttons in the control panel to change the displayed value and determine whether or not to use the previous settings.

If the chosen value is YES, the previous set values of the following parameters will be displayed, one after the other, on the second text line:

- Working neg. Pressure.

- Upper / Lower Limit.
- Max. Flow.
- Work / Pause Time (displayed only if the previous Mode of Operation is Intermittent).

After viewing the previous settings, the following options are available:

- Press ↓ to go to Stand-by screen.
- Press FUNC to adjust treatment settings.

Pressing FUNC will transfer the user to the next function in the menu. In this case, the flickering values will be the values chosen in the previous treatment, and the user will be able to change them.

5.1.3. Mode of Operation

When entering the Mode of Operation function, the following screen is displayed:

The default mode of operation, Cyclic-Continuous mode, is flickering.

There are two optional modes of operation: Intermittent or Cyclic- Continuous.

Use the up and down scroll arrow buttons in the control panel to change the flickering mode to the required mode of operation. The guiding messages in the second line change according to the selected mode.

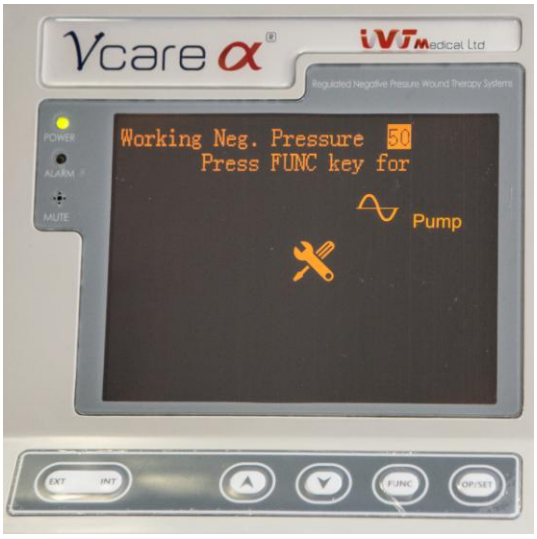
Press OP/SET to finalize your selection. The value stops flickering.

Press ↓ to continue to the next parameter.

See Clinical guidelines and Vacuum Operation Modes sections before choosing the Mode of Operation.

5.1.3.1. Cyclic-Continuous Working Negative Pressure

The following screen is displayed:



The default value of cyclic-continuous working neg. pressure is flickering. The default baseline pressure in cyclic-continuous mode and available baseline pressure values according to the risk of bleeding are detailed in the table below:

Risk of Bleeding	Cyclic – Cont. Baseline Pressure Default [mmHg]	Displayed Optional Baseline Levels [mmHg]
High	50	40, 50
Moderate	75	40, 50 or 75
Low	75	40, 50, 75, 100 or 125

The baseline working neg. pressure in cyclic-continuous mode oscillates within the range of approximately ±20% from the baseline neg. pressure. Use the up and down scroll arrow buttons in the control panel to change the flickering value.

Press OP/SET button to finalize your selection. The displayed value stops flickering.

Press Func shortly to enter advanced settings in order to select one of the additional baseline pressures. The pressure will be displayed on the screen. Use the UP and Down scroll arrow buttons in the control panel to change the displayed value.

Press OP/SET button to finalize your selection. The value stops flickering.

- It is recommended to use external vacuum source as possible. When using the internal pump in cyclic continuous mode, the pump will pause for 1 minute every 10 minutes of operation.
- Following the determination of the Cyclic-Continuous base- line working neg. pressure, pressing ↓ will switch to the last function in this menu: Start Working. Pressing the OP/SET button will transfer the user to the stand-by screen (see Main screens chapter).

5.1.3.2. Intermittent / Continuous Mode

5.1.3.2.1. Working Negative Pressure Determination

When entering the Working neg. Pressure determination function, the following screen is displayed:

Common working neg. pressure values are displayed in the first line and the displayed default neg. pressure value is flickering. The available working neg. pressure and default value are determined according to the Risk of Bleeding (see the table below for detailed default working neg. pressure and displayed values). In addition, the working neg. pressure can be linearly adjusted within the range of 30-200 mmHg, and is limited in accordance to the Risk of Bleeding evaluation, as described in the table below.

Risk for Bleeding	Default Working Pressure [mmHg]	Displayed Pressure Values [mmHg]	Working Pressure Range [mmHg]
High	60	40, 50, 60	30-65
Moderate	70	60, 70, 80	30-90
Low	80	60, 80, 100	No limit (30-200)

Use the up and down scroll arrow buttons in the control panel to change the flickering value and determine the required Working neg. Pressure.

Press OP/SET to finalize your selection. The value stops flickering.

For advanced pressure setting, press FUNC shortly. The working neg. pressure value will be displayed in [a].

Use the up and down scroll arrow buttons in the control panel to change the displayed value and determine the required Working neg. Pressure. Press OP/SET to finalize your selection. The displayed value stops flickering.

Press ↓ to continue to the next parameter.

5.1.3.2.2. Lower Limit

When entering the Lower Limit function, the following screen is displayed:

The default lower limit value is flickering.

The default value of the lower limit is pre-set to be 10 mmHg below the working neg. pressure and the range of the lower limit can be linearly adjusted within the range of 30 mmHg to the default value.

For advanced Lower Limit settings, press FUNC shortly. This allows the user to change the Lower Limit to a different value in the pre-set available range. Use the up and down scroll arrow buttons in the control panel to change the displayed value and determine the required lower limit.

Press OP/SET button to finalize your selection. The displayed value stops flickering.

Press ↓ to continue to the next parameter.

Warning: do not set low values of lower limit in order for the system to detect improper vacuum applied to the wound.

In case the pressure applied by the device will be lower than the lower limit value, an alert will be generated (see the Alarms chapter for more details).

5.1.3.2.3. Upper Limit

When entering the Upper Limit function, the following screen is displayed:

The default upper limit value is flickering.

The default value of the upper limit is pre-set to be 15 mmHg above the working neg. pressure and the range of the allowed upper limit is pre-set according to the Risk of Bleeding and Working neg. Pressure (WP) selection as follows:

Risk of Bleeding	Upper Limit Range
High	WP+15 to 80
Moderate	WP+15 to 105
Low	WP+15 to 215

For advanced Upper Limit settings, press FUNC shortly. This allows the user to change the Upper Limit to a different value in the pre-set available range.

The upper limit is displayed in [a].

Use the up and down scroll arrow buttons in the control panel to change the displayed value and determine the required upper limit.

Press OP/SET button to finalize your selection. The displayed value stops flickering.

Press ↓ to continue to the next parameter.

 Warning: do not set high values of upper limit in order for the system to detect improper vacuum applied to the wound.

 In case the vacuum applied by the device will be higher than the upper limit value, an alert will be generated (see Alarms chapter for more details).

5.1.3.2.4. Working Time Determination

When entering the Working Time determination function, the following screen is displayed:

Common working time values are displayed in the first line: 1-5 minutes. The default working time value, 3 min, is flickering.

Use the up and down scroll arrow buttons in the control panel to change the flickering value and determine the required working time.

Press OP/SET button to finalize your selection. The value stops flickering.

For advanced work time setting, press the FUNC button shortly. The work time value will be displayed in [a].

Use the up and down scroll arrow buttons in the control panel to change the displayed value and determine the required working time. The working time can be linearly adjusted in the range of 1-15 min.

Press OP/SET button to finalize your selection. The displayed value stops flickering.

Press ↓ to continue to the next parameter.

- See the Clinical guidelines for recommended intermittent treatment parameters.
- For an intermittent therapy, the determined value is the length of therapy's time segments.
- For continuous therapy, choose the intermittent operation mode and make sure that the device is connected to an

external vacuum source. This will enable the user to set the pause time value to zero.

5.1.3.2.5. Pause Length Determination

When entering the Pause Length determination function, the following screen is displayed:

Common pause time values are displayed in the first text row: 0-3 minutes. The default pause time value, 1 min, is flickering.
Use the up and down scroll arrow buttons in the control panel to change the flickering value and determine the required pause time.
Press OP/SET button to finalize your selection. The value stops flickering.
For advanced pause time setting, press FUNC shortly. The pause time value will be displayed in [a].
Use the up and down scroll arrow buttons in the control panel to change the displayed value and determine the required pause time. The pause time can be linearly adjusted within the range of 0-10 min.
Press OP/SET button to finalize your selection. The displayed value stops flickering.
Press ↓ to continue to the next parameter.

For continuous therapy, make sure that the device is connected to an external vacuum source. This will enable the user to set the pause time value to zero. The device cannot operate on continuous mode when using the internal pump.

Warning: Avoid long pause of the vacuum. As the Vcare α® is operating, fluids are discharged and constantly evacuated from the wound. Once the vacuum is halted, the system is at risk of becoming occlusive, which might lead to infection.

5.1.4. Max Flow Rate Determination

When entering the Max. Flow function, the following screen is displayed:
The default or pre-set (in treatment menu) value of maximal allowed flow [ml/hr] is flickering.
This function enables the determination of maximal flow rate of fluids [ml/hr] allowed from the patient's wound to the Vcare α® canister.
In order to respond immediately in case of bleeding, the default (and recommended) value for maximal flow is up to 100 ml/hour. If a patient's wound is treated using liquids, which need to be collected to the canister as part of the treatment procedure and there is no risk of bleeding ('Low') according to the physician, a higher value can be determined: 200 ml/hour or 300 ml/hour.
It is highly recommended to keep the default value of up to 100 ml/hr of flow. Higher flow values may limit the detection of acute bleeding.

Use the up and down scroll arrow buttons to change the flickering value and determine the maximal allowed flow from the wound to the canister.
Press OP/SET to finalize your selection. The value stops flickering.
Press FUNC to continue to the next function.

For the safety of the patient, if you have previously evaluated the Risk of Bleeding as High or Moderate, you will not be able to change the Max Flow to be higher than 100 ml/hr.

In case the accumulated fluid volume in the canister exceeds the maximal volume allowed during operation, an alarm will be activated and the vacuum operation will be shut down (see the Alarms and Alerts chapter for more details).

5.1.5. Start Working

When entering the Start Working Screen, the following screen is displayed:

Press OP/SET to go to the Stand-by screen.
Press ↓ to return to the first function in the treatment menu.
Press FUNC for approximately 5 seconds in order to go to the set-up menu.
Note: as vacuum operation is initiated, the low vacuum alert will be displayed on the screen until the working negative pressure stabilizes on the desired level, unless it cannot be stabilized due to leakage.

5.2. System Set-Up Menu

In menu selection screen, press FUNC for approximately 5 seconds in order to enter System Set-Up Screen. While setting treatment parameters, symbol no. 6 appears on the screen as an indication.

Using the control panel in system set-up menu:

At any stage of system set-up, when a flickering value is displayed, press shortly on the control panel OP/SET button in order to select the displayed value for the current treatment parameter, or, use the up and down scroll arrow buttons to brows between available values for the current parameter and then press OP/SET button to select the required value.

After pressing OP/SET, the displayed value will stop flickering.

When the value is not flickering, press the Down Scroll arrow button shortly in order to continue to the next function.

At any stage of the system set-up menu, pressing the FUNC button for approximately 5 seconds will switch to the Stand-By screen. The user can then choose to start the vacuum operation by pressing OP/SET.

5.2.1. F1: Language

The language function displays the current language used for user interface in the Vcare α® unit.

Press the Down Scroll button in order to continue to the next function.

5.2.2. F2: Alarm Mode Determination

The displayed default alarm mode, Audio and Visual alarms (A&V), is flickering.

Use the up and down scroll arrow buttons in the control panel to change the flickering value and select the desired alarm mode:

5.2.2.1. Visual (Visual alarm only)

The alarms indication will be only visual (flickering indication light and general alarm symbol). A relevant message will be displayed on the screen.

5.2.2.2. A&V (Audio and Visual alarms)

In any case which necessitates alarm generation, the indication will be both auditory (A repetitive beeping sound) and visual (flickering

indication light and general alarm symbol) along with a relevant message.

In order to monitor the wound healing and treatment process, it is important for the care-giver to be aware to all alarms and indications regarding the suction apparatus and treatment. Therefore, it is advised to keep the default alarm setting, which is an audio and visual alarm. Any change of alarms setting may prevent from the care-giver the detection of critical indications regarding the vacuum treatment and may lead to misuse of the suction apparatus.

For the safety of the patient, if you have previously evaluated the Risk for Bleeding as High or Moderate, you will not be able to change the Alarms from the default setting (Audio & Alarms).

Press OP/SET button to finalize your selection. The value stops flickering.
Press Down Scroll arrow in order to continue to the next function.

For more information regarding alarms types and operation, see the alarms chapter.

5.2.3. F3: Negative Pressure Units Determination

The default pressure units setting, mmHg, is flickering in the first text line.
Use the up and down scroll arrow buttons in the control panel to change the flickering value and determine the systems pressure units: mmHg or KPa.
Press OP/SET to finalize your selection. The value stops flickering.
Press Down Scroll arrow to continue to the next function.

5.2.4. F4: Battery Voltage Display

The current battery voltage (in volts) is displayed on the screen.
Press Down Scroll arrow in order to continue to the next function.

5.2.5. F5: Total Pump Operation Time Display

The total working hours of the engine are displayed on the screen.
Press Down Scroll arrow in order to continue to the next function.

5.2.6. F6: Software Version Display

The current version of the system software is displayed on the screen.

Press the Down Scroll button in order to continue to the next function.

5.2.7. F7: Back Screen

5.2.7.1. Incase reaching from treatment menu. First line: "To Treatment menu press OP/SET" – returning to the last screen we had been in the treatment menu, before reaching the set-up menu.
Second line: "To start over press FUNC" – start over the set-up menu.

5.2.7.2. Incase reaching from Stand-By screen (after setting all parameters in the treatment menu)
First line: "To start treatment press OP/SET" – returning to the "stand-by screen".
Second line: "To start over press FUNC" – start over the set-up menu

5.2.7.3. Incase reaching from Stand-By screen (after yes was chosen at "use previous setting" screen)
First line: "To Treatment menu press OP/SET" returning to the risk of bleeding screen.
Second line: "To start over press FUNC" – start over the set-up menu

Note: as vacuum operation is initiated, the low vacuum alert will be displayed on the screen until the working negative pressure stabilizes on the desired level, unless it cannot be stabilized due to leakage.

Vcare α® quick instructions guide

1. Verify that the wound doesn't actively bleed.
2. Insert the collection canister into the canister socket sound….
3. Connect the canister proximal tube to the collection canister.
4. When using mobile stand, make sure the Vcare α® unit is securely connected to the mobile stand and that the lock-pin is closed.
5. Connect the Vcare α® unit using a suitable power adapter (see specifications chapter) to the wall electrical outlet.
6. Turn the Vcare α® unit on.
7. Select External/Internal vacuum source (it is advised to use external vacuum source as possible to avoid burnout of the internal pump).
8. Set the treatment parameters using the Treatment Setting Menu section.

9. Apply wound dressing to the wound (see "Setup for dressing application" for detailed instructions).
10. Connect the canister proximal tube to the distal connecting tube via the two way tube connector.
11. Activate vacuum using the OP/SET button on the control panel.
12. Verify that the wound dressing is sealed (inspect the sponge to be evenly condensed/squeezed.).
13. Check the display and verify that the neg. pressure applied is according to the pre-set value (a minor fluctuation of +/-5 mmHg in actual pressure should be expected).
14. Patient and wound status should be monitored regularly according to the clinical condition of the wound.

 When the device is operated by the internal battery, operation of approximately 1 hour is expected.

Alarms and Alerts

Vcare α® Alarm system

The Vcare α® system has two kinds of alarm signals:

- Visual alarm- consists of an indication LED (red/ yellow) and of the following alarm condition symbol: (Alarm sumbol no. 1 from the symbols description table).
- Auditory alarm- repetitive beeping sound produced by a buzzer. The beeping frequencies and inter-burst intervals change according to alarm condition priority (High and Low) in order for the care-giver to identify the priority of the alarm condition from distance and act accordingly.

 In order to hear the auditory alarm the device must be operated in a quite environment with background noise of no more than 45-50dB.

 For further information, see buzzer specification in the specifications section.

The user is able to choose between a visual alarm and a visual & auditory alarm signals.

1. **Alarm conditions**

1.1. Critical battery alarm

Description: this alarm is initiated when battery voltage is too low to support operation of the system. In this case, vacuum operation is shut down and alarms are set.

Priority: High.

Visual alarm signal: flickering red indication LED, alarm signal no. 1- general alarm signal from screen symbols description table.

Auditory alarm signal: high frequency repetitive beeping sound.

Additional signals: general warning status (symbol no. 7), low battery status (symbol no. 8 with no black bars) from screen symbols description table.

Information sentences: First line: “Critical Battery Condition”, Second line: "Connect to main source”.

To resolve this alarm: connect the Vcare α® unit to the wall outlet using a suitable external power adapter (see specifications section) and press OP/SET to resume treatment.

Battery malfunction is expected if the system is not connected to an external power adapter immediately.

In case this alarm is repeated after following these instructions, contact your service provider.

1.2. High flow alarm

Description: this alarm is initiated when the system detects that the accumulated liquids volume in the collection canister exceeds the pre-defined maximal volume per hour.

In this case, vacuum operation is automatically shut down and alarms are set.


High flow stops the vacuum operation.


It will not be possible to re-activate the device by pressing the OP/SET button. For re-operation, the device will have to be re-started.

Priority: High.

Visual alarm signal: flickering red indication LED, alarm signal no. 1- general alarm signal from screen symbols description table.

Auditory alarm signal: high frequency repetitive beeping sound.

Additional signals: general warning status (symbol no. 7) from screen symbols description table.

Information sentences: First line: “Watch for possible bleeding”, Second line: “Turn off for reactivation”.

To resolve this alarm

- Turn the Vcare α® unit off.
- A physician must inspect the patient to find if there is active bleeding from the wound.
- Therapy should not be re-activated before an extensive physician inspection and re-evaluation of active bleeding and the risk of bleeding from the wound.
- If there are still signs for bleeding, apply compressive pressure on the wound and evaluate the need for further intervention.

In case this alarm is repeated after following these instructions, contact your service provider.

1.3. Extreme High Vacuum alarm

Description: this alarm is initiated when the applied neg. pressure is:

- 20 mmHg above upper limit for 30 seconds or;
- Above the upper limit but below upper limit + 20 mmHg for 1 more minute (meaning 1.5 minutes from the high vacuum alert activation).

In this case, vacuum operation is automatically shut down.

Priority: High.

Visual alarm signal: flickering red indication LED, alarm signal no. 1- general alarm signal from screen symbols description table.

Auditory alarm signal: high frequency repetitive beeping sound.

Additional signals: general warning status (symbol no. 7) from screen symbols description table.

Information sentences: First line: “Hazardous operation level”, Second line: (1) “Caution!” (2) “Extreme high op. zone!” (3) “Turn off for re-activation” (where (1), (2) and (3) are presented one after the other for 5 seconds each).

To resolve this alarm:

- Turn the Vcare α® unit off.

- In case an external vacuum source is connected, reduce the pressure from the external vacuum source to ~10 mmHg above the working negative pressure level. If not;
- Restart the device.

In case this alarm is repeated after following these instructions, contact your service provider.

In order to confirm that the preset vacuum is actually applied to the wound, it is recommended that together with the treatment operational setting, the care-provider should inspect the sponge to be evenly condensed/ squeezed.

1.4. High Vacuum alarm

Description: The applied neg. pressure is above the upper limit but does not exceed upper limit + 20 mmHg, for continuously 30 seconds.

Priority: Low.

Visual alarm signal: constant yellow indication LED, alarm signal no. 1- general alarm signal from screen symbols description table.

Auditory alarm signal: low frequency repetitive beeping sound.

Additional signals: general warning status (symbol no. 7) from screen symbols description table.

Information sentences: First line: "Caution! High level vacuum". If connected to external suction, the Second line displays: (1) "Reduce external suction" (2) "to Working Pressure" (where (1) and (2) are presented one after the other for 5 seconds each).

To resolve this alarm:

- Stop the vacuum operation.
- Turn the Vcare α® unit off.
- In case an external vacuum source is connected, reduce the pressure from the external vacuum source to ~10 mmHg above the working negative pressure level. If not;
- Restart the device.

In case this alarm is repeated after following these instructions, contact your service provider.

In order to confirm that the preset vacuum is actually applied to the wound, it is recommended that together with the treatment operational setting, the care-provider should inspect the sponge to be evenly condensed/ squeezed.

 Warning: failure to respond to this alarm may lead to tissue damage.

If not resolved immediately, high vacuum condition would eventually turn to Extreme High Vacuum condition.

1.5. Low Vacuum alarm

Description: The applied neg. pressure is less than 25 mmHg from the lower limit for continuously 30 seconds.

Priority: Low.

Visual alarm signal: constant yellow indication LED, alarm signal no. 1- general alarm signal from screen symbols description table.

Auditory alarm signal: low frequency repetitive beeping sound.

Additional signals: general warning status (symbol no. 7) from screen symbols description table.

Information sentences: First line: “Ineffective vacuum level”.

To resolve this alarm:

- Inspect the sponge, drape stripes, tubing and collection canister for possible leakage.
- Make sure that the canister is positioned properly in the canister socket.
- If connected to an external vacuum source, make sure that the pressure from the external vacuum source is above the working pressure.
- In case the applied vacuum is ~0 mmHg but the pump is working, contact your service provider for hydro-gel filter inspection.

In case this alarm is repeated after following these instructions, contact your service provider.

 Warning: Do not leave a wound covered without effective vacuum for long time periods.

 Warning: failure to respond to this alarm may exacerbate wound infection.

If not resolved immediately, low pressure condition may eventually turn to Extreme low pressure condition.

1.6. Extreme Low Vacuum alarm

Description: the applied neg. pressure is less than 25 mmHg for continuously 15 minutes.

Priority: Low.

Visual alarm signal: constant yellow indication LED, alarm signal no. 1- general alarm signal from screen symbols description table.

Auditory alarm signal: low frequency repetitive beeping sound.

Additional signals: general warning status (symbol no. 7) from screen symbols description table.

Information sentences: First line: "Ineffective vacuum level", Second line: (1) "Check for leakage" (2) "and tubing connectivity" (where (1) and (2) are presented one after the other for 5 seconds each).

To resolve this alarm:

- Inspect the sponge, drape strips, tubing and collection canister for possible leakage.
- Make sure that the canister is positioned properly in the canister socket.
- If connected to an external vacuum source, make sure that the pressure from the external vacuum source is above the working pressure.
- In case the applied vacuum is ~0 mmHg but the pump is working, contact your service provider for hydro-gel filter inspection.

In case this alarm is repeated after following these instructions, contact your service provider.

 Warning: Do not leave a wound covered without effective vacuum for long time periods.

 Warning: failure to respond to this alarm may exacerbate wound infection.

1.7. Low Battery alarm

Description: this alarm is initiated when battery voltage is low and approximately 10 minutes of operation are left.

Priority: Low.

Visual alarm signal: constant yellow indication LED, alarm signal no. 1- general alarm signal from screen symbols description table.

Auditory alarm signal: low frequency repetitive beeping sound.

Additional signals: general warning status (symbol no. 7), low battery status (symbol no. 8 with 1 black bar) from screen symbols description table.

Information sentences: First line: "Low battery", Second line: "connect to main source".

To resolve this alarm: connect the Vcare α® unit to the wall outlet using a suitable external power adapter (see specifications section).

In case this alarm is repeated after following these instructions, contact your service provider.

 Warning: Do not leave a wound covered without effective vacuum for long time periods.

To avoid battery malfunction, connect the system to an external power adapter immediately.

 Warning: this device should be operated with a power adapter which complies with the specifications detailed in the external power adapter specifications section.

 Warning: The internal battery is not accessible for users. In case that battery malfunction is suspected, Contact IVT Medical Ltd. for a certified technical personnel.

If not resolved immediately, low battery condition would eventually turn to Critical battery condition.

1.8. Near Full Canister alarm

Description: The liquid volume in the collection canister is 650 ml.

Priority: Low.

Visual alarm signal: constant yellow indication LED, alarm signal no. 1- general alarm signal from screen symbols description table.

Auditory alarm signal: low frequency repetitive beeping sound.

Additional signals: general warning status (symbol no. 7) and canister fill status- indicates the canister fill level (symbol no. 10) from screen symbols description table.
Information sentences: First line: “Canister near full capacity”.

1.9. Full Canister alarm

Description: As the liquid volume reaches 700 ml, vacuum operation is automatically shut down.
Priority: Low.
Visual alarm signal: constant yellow indication LED, alarm signal no. 1- general alarm signal from screen symbols description table.
Auditory alarm signal: low frequency repetitive beeping sound.
Additional signals: general warning status (symbol no. 7) and canister fill status- indicates the canister fill level (symbol no. 10) from screen symbols description table.
Information sentences: First line: “Full canister”, Second line” (1) “Turn system off (2) replace canister and” (3) “Re-activate treatment” (where (1), (2) and (3) are presented one after the other for 5 seconds each).

Additional signal: symbol number 9 appears on the screen.
To resolve this alarm:

- Stop the vacuum operation.
- Turn the Vcare α® unit off.
- Replace the collection canister as instructed in replacing the collection canister section in this manual.
- Restart the device.

In case this alarm is repeated after following these instructions, contact your service provider.

Vacuum operation stops automatically when the fluids level in the canister is 700 ml.
In case this alarm is repeated, contact your service provider.
For further information regarding the alarm system, please refer to the alarm appendix.
In case of mechanical or electronic failure of the device and for any query or improvement suggestion contact your service provider.

2. Alert conditions

2.1. High Vacuum alert

Description: the applied neg. pressure is above the upper limit.

Alarm signals: none.

Additional signals: general warning status (symbol no. 7) from screen symbols description table.

Information sentences: Second line: (1)"Caution: Pressure is" (2) "above upper limit" (where (1) and (2) are presented one after the other for 5 seconds each).

To resolve this alert:

- Stop the vacuum operation.
- Turn the Vcare α® unit off.
- If connected to an external vacuum source, reduce the pressure from it
- Restart the device.

In case this alarm is repeated after following these instructions, contact your service provider.

In order to confirm that the preset vacuum is actually applied to the wound, it is recommended that together with the treatment operational setting, the care provider should inspect the sponge to be evenly condensed/ squeezed.

Warning: failure to respond to this alert may lead to High Vacuum alarm condition.

2.2. Low Vacuum alert

Description: the applied neg. pressure is below the lower limit.

Note: as vacuum operation is initiated, the low vacuum alert will be displayed on the screen until the working negative pressure stabilizes on the desired level, unless it cannot be stabilized due to leakage.

Alarm signals: none.

Additional signals: general warning status (symbol no. 7) from screen symbols description table.

Information sentences: Second line: (1)"Caution: Pressure is" (2) "below lower limit".

To resolve this alert:

- Inspect the sponge, drape stripes, tubing and collection canister for possible leakage.
- Make sure that the canister is positioned properly in the canister socket.

- Make sure that the pressure from the external vacuum source is above the working pressure.

In case this alarm is repeated after following these instructions, contact your service provider.

 Warning: failure to respond to this alert may lead to Low pressure alarm condition.

3. Maintenance and Error alerts

The maintenance and error alerts are displayed, when necessary, following the self test screen. The user can choose to postpone the alert to a later stage (Postpone) or to resolve it immediately (Done) by using the scroll arrow buttons and finalizing the selection by pressing the OP/SET button. The user needs to follow the instruction in user manual section 3.1-3.3. Only after conducting all the required procedures the user need to press the "Done" button. The default selection of this alert is “Postpone”.

3.1. Device Service and Maintenance

Description: in order to maintain the device performance and effective operation, the Vcare α® unit should go through routine maintenance inspection. Routine maintenance is required after 5000 hours or following one year of engine operation (whichever comes first).

Alarm signals: none.

Additional signals: general warning status (symbol no. 7) from screen symbols description table (the signals will appear only after 4500 hours of operation).

Information sentences: First line: “Postpone Done”, Second line: (1) “Maintenance required”, (2) “Refer to user manual”:

 To resolve this alert:

Contact IVT Medical Ltd. for a certified technical personnel inspection of:

1. Internal and external fuses inspection
2. Battery voltage measurement of maximal voltage and inspection for possible leakage and corrosion
3. Replacing the internal pump

4. Inner hydro-gel filter replacement
5. Trapper replacement
6. Clear PVC tubes inspection and replacement if indicated
7. Fan cleaning
8. Tightening of loose screws
9. Alarm Buzzer and LEDs inspection
10. Pressure sensors validation
11. Screws on the outer shell should be inspected for fatigue and replaced if necessary.

 For further guidance and maintenance instructions, refer to Maintenance chapter in this manual.

Error alerts

3.2. Err01: Extreme High Vacuum.

Description: this alert is initiated In case Extreme High Vacuum alarm is repeated more than 3 times is 24 hours.

Alarm signals: none.

Additional signals: general warning status (symbol no. 7) from screen symbols description table.

Information sentences: First line: "Error Alert Err01 Postpone Done", Second line: “Refer to user manual for details".

 To resolve this alert:

- If connected to external suction, make sure that external vacuum is 50 mmHg above the working neg. pressure (which were determined) and check if this error alert is repeated.
- Reduce the external vacuum level to 10 mmHg above the working neg. pressure.
- If the alarm is repeated, contact IVT Medical Ltd. certified technical personnel for inspection of the pressure regulation valves.
-

3.3. Err02: Flow LEDs error

Description: the canister fill level bars display is based on the internal canister fill LEDs detection. The device automatically tests each one of the 16 flow LEDs (sensors) functionality every time it is turned on. In case the LEDs self-test detects a

failure in one (or more) of the LEDs in two sequential operations, an error alert will be displayed.

Alarm signals: none.

Additional signals: none

Information sentences: First line: "Error Alert Err02 Postpone Done", Second line: “Refer to user manual for details.

To resolve this alert:

- Check for correlation between the canister fill level bars on the screen display and the actual liquid volume inside the canister (each bar represents 100 ml of liquid). In case the display and the actual liquid volume are correlated, the sensors are not damaged and you may proceed with the vacuum operation. In case they are not correlated, turn the unit off and proceed all to the next steps:
- Turn off the deviceEject the current canister out of the canister socket (according to "replacing the collection canister" section in this manual)
  - Turn on the device and check if this error alert is repeated (check for errors in the leds sensors).If error alert 02 is not displayed, the sensors are not damaged and you may proceed with the vacuum operation.
  - If error alert 02 is displayed, turn the unit off and contact your service provider.
  - Turn off the device
- Insert a new empty canister into the canister socket.
- Turn the device on
  - If error alert 02 is not displayed, the sensors are not damaged and you may proceed with the vacuum operation.
  - If error alert 02 is displayed, turn the unit off and contact your service provider.

Vcare α® system specifications

Technical Specifications

Classification: Medical Electrical System

Vcare α® unit Specifications

- Operation mode: Continuous

- Applied part: type BF (sponge, surrounding drape and drape stripes)
- IPX0 Not protected against harmful effects of water

External power adapter:

- UL or TUV or CSA medical grade Power Adapter

Vcare α® Unit

Dimensions: L 37 cm x H 22.8 cm x W 22 cm

Weight: 5.9 kg

Input: ~15V DC, MAX 3.3A

Max. Power consumption: ~75W

Max. Inlet vacuum: 200 mmHg / 26.7 KPa.

Internal Battery

Type: Sealed lead acid battery.

Nominal Voltage: approximately 12V.

Maximal voltage (fully charged battery): 14.9 V

Rated Current : 3.2A

Dimensions: L 13.4 cm X H 6.1 cm X W 6.7 cm

Operation time: ~1 hour.

Charging time from critical to fully charged condition: ~16 hours.

To avoid battery malfunction, connect the Vcare α® unit to an external power adapter when the device is turned off. Battery voltage continues dropping when the device is off.

Battery warrantee is provided by IVT Medical Ltd for one year from Vcare α® purchasing.

Internal Suction Pump

Max. Vacuum: 650 mmHg / 80 KPa

Rated current: 3.1A

Ambient temperature: ~0-40°C.

Max. operation hours: 5,000.

The Vcare α® unit must be returned to IVT Medical at the end of its operational life, i.e following 5,000 pump operation hours.

Therapy Adjustment Options

Negative Pressure Range: 30-200 mmHg

Modes of Operation: Cyclic-Continuous, Continuous or Intermittent.

External fuse

Quick blow glass fuse 4A / 250V

External Wall Suction Tube

Length: 1.7 meters

The external vacuum source connector can tolerate vacuum of up to 760 mmHg; however, the recommended input vacuum is max. 200 mmHg.

Internal Fuse

Quick blow fuse 5A / 250V

Buzzer

Manufacturer: Mallory Sonalerts products INC.

Sound pressure range @ 10 cm: 88 dB, @ 1 m: 70 dB.

High Priority Alarms

Specifications: *Beep*, Pause 100 ms, *Beep*, Pause 100 ms, *Beep*, Pause 300 ms, *Beep*, Pause 100 ms, *Beep*, Pause 500 ms, *Beep*, Pause 100 ms, *Beep*, Pause 100 ms, *Beep*, Pause 300 ms, *Beep*, Pause 100 ms, *Beep*.

Repeat every 2.5 sec's.

Beep "on" time is 100 ms.

Low priority alarms

Specifications: *Beep*, Pause 200 ms, *Beep*.

Repeat every 5 minutes.

Beep "on" time is 200 ms.

Designed to Meet IEC 60601-1-8

External Power Adapter

The Vcare α® unit can be connected to the main power supply through a power adapter. The power adapter is not part of the Vcare α® device but it is mandatory to use it. The power adapter must comply with the specifications described below.

Input Voltage: 100-240 V

Max. input current: 1.5A

Output Voltage: approximately 15V DC

Max. output current: 3.3 A

Leakage current: 0.5mA / 240VAC

Frequency: 50-60 Hz

Max. Power Consumption: approximately 50 W

UL / TUV / CSA medical grade certified.

Operation Temperature: ~0-65 °C

Operation relative humidity: ~20%-90%

Storage Temperature: ~(-20)-85 °C

Storage relative humidity: ~10%-95%

Accuracy of Displayed Values

Max. Error of pressure sensor: 2.5%.

Pressure Display error: 0.01 mmHg/ KPa

Canister Fill level Display error: 50 ml.

Battery Voltage Display error: 0.01 V.

Storage and Environmental Conditions

Storage and Transportation Temperature Range: (-15)-80 °C

Storage and Transportation Relative Humidity Range: 0-50%

Storage and Transportation Atmospheric Pressure: 700-1060 hPa

Operational Temperature Range: 0-40 °C

Operational Relative Humidity Range: 0-50%

Operational Atmospheric Pressure: 700-1060 hPa

Prior to storage of the device, make sure the battery is fully charged (14.9 Volt). For short time periods the device can be stored in temperatures of -5 to 50 degrees Celsius.

In case the device has been stored in temperatures below freezing, bring the system to room temperature prior using.

Disposables Specifications

Collection Canister

Volume: 800 ml

Trapper

Volume: 33ml

Canister Proximal Tube

The canister proximal tube is made of PVC (Poly-Vinyl-Chloride).

Length: 1.7 m

Distal Connecting Tube, Tube Adapter and Attachment Drape

The distal connecting tube is made of PVC (Poly-Vinyl-Chloride).

Tube length: 500 mm ± 15 mm

Each tube is supplied with a tube stopper to block the tubes when temporary disconnecting the tubes or before discarding the kit to avoid spillage of fluids.

Each tube is supplied with a cup to block the tubes when temporary disconnecting the tubes or before discarding the kit to avoid spillage of fluids.

A Tube adapter is attached to the bottom end of the tube.

The Tube adapter has an inlet which enables tube washing during vacuum operation in case of tube blockage.

The Attachment drape is made of 3 layers: the upper layer is made of LDPE (Low-Density polyethylene), the middle layer is PU (polyurethane) and the bottom layer is glue.

The Attachment drape is attached to the irrigation port.

Sponge

The bottom layer of the sponge (in contact with the wound surface) is open cell multi-channel polyurethane foam that allows for liquids and air transformation from one side of the sponge to the other. The upper layer of the sponge is a non-permeable polyurethane sealing drape that seals the wound together with the drape strips.

Drape stripes

The drape stripes are made of 3 layers: the upper layer is made of LDPE (Low-Density polyethylene), the middle layer is PU (polyurethane) and the bottom layer is glue.

The sponge and drape stripes are available in the following dimensions:

Sponge Size (W*L)	Drape Size (W)	Drape Size (L)
100 × 100 mm	150×55 mm	150×55 mm
100 × 200 mm	150×55 mm	250×65 mm
150 × 200 mm	200×55 mm	250×65 mm
300 × 200 mm	350×65 mm	250×65 mm
400 × 450 mm	450×65 mm	500×65 mm

A Y-shaped connector is provided with the two large wound dressing sets.

Disposables Storage Conditions

Store away from direct sunlight in a cool dry place. Optimal storage conditions at temperatures between 10-28°C and relative humidity between 40-70%.

Maintenance and Routine Inspections

Cleaning the Unit

Cleaning and disinfection of the device between different patients is necessary and should be done in accordance with the guidelines below:

1. Unplug the device from the external power adapter and external vacuum source.
2. Inspect the unit for any signs of contamination.
3. Gently wipe the LCD screen using a soft cloth and a designated LCD detergent. The cloth should be damp but not dripping.
4. Using a soft cloth and 70% alcohol, gently wipe down the outer surface of the device.
5. Use a low-level cleaning agent or disinfectant and ensure its compatibility with plastics. Follow manufacturer's guidelines for use of cleaning agents.
6. Use another fiber-free damp cloth to remove any remaining solution from the device surface.
7. Use a clean and dry soft cloth to wipe the outer device surface.
8. Do not use plastic solvents or abrasives.

Warning: Fluids should not be allowed to enter into the device. Do not use unnecessary liquids to clean the device. If any liquids penetrate the device contact your local authorized provider.

Maintenance Procedures

In order for the Vcare α® unit proper and safe operation, routine maintenance and system components inspection is required. The maintenance procedures should be done only by trained and authorized technical personnel.

Prior to Operation

Responsibility: operator.

1. Make sure that the external wall suction tube is not damaged and properly connected to the unit.
2. Inspect the unit for any signs of contamination.
3. If there is any sign of contamination, clean the unit according to cleaning the unit section in this manual.

Warning: do not connect the Vcare α® unit to a damaged external power adapter.

Alarm Appendix

Generation of Alarm Signal for Two or More Alarm Conditions

- When there are several conditions that require alarm signals, the alarm system generates the signals of the highest priority alarm condition. The text lines on the screen display information regarding the higher priority condition and the information symbols and measured value of each condition will be displayed on the screen.
- If the alarm conditions are of the same priority, the symbols and measured values of all conditions will be displayed on the screen. The text lines will display the information sentences according to the following internal ranking:
    - For high priority alarms
    1. Extreme high vacuum/High flow (whichever is initiated first)
    2. Critical battery
    - For low priority alarms
    1. High/Low vacuum
    2. Full canister
    3. Low battery

Alarm Preset

The Vcare α® treatment parameters are affected by the operator's evaluation of the patient's Risk of Bleeding. There are three possible such risks: High, Moderate and Low. As the user chooses the appropriate Risk of bleeding based on his experience and judgment, other treatment parameters are limited accordingly. The user can set the parameters to default values or to a different value within a pre-programmed range. The parameters ranges and default values were chosen carefully, while taking into consideration possible harms and hazards to the patient. Therefore, even if the operator sets the parameters to extreme values, these values are still in the allowed range for the current treatment. Alarm limits are limited by the Risk of bleeding as well.

Alarm Limits

Prior to each treatment, the operator sets the treatment parameters within a possible pre-programmed range according to the Risk of bleeding, which defines the limits of alarm triggering events. The operator sets the maximal desired flow, the working pressure and its upper and lower limits. These parameters, along with the chosen Risk of bleeding, determine the alarm limits.

Alarm Inactivation States

The Vcare α® system has two alarm indications: audio and visual, while the user can adjust the alarm indication to audio & visual or visual.

- When the auditory alarm is off (i.e. the user chose only Visual alarm signal), the Audio off alarm signal (alarm signal no. 2 from screen symbols description table) is constantly displayed on the screen during treatment. In case that an alarm condition requiring alarm signal is generated, the audio off signal will switch with the alarm condition signal (alarm signal no. 1), repetitively. High priority alarms will generate both audio and visual alarms, regardless to the user alarm setting.

Alarm System Security

The suction apparatus of the Vcare α® is controlled by a firmware – pre-installed on the device's microcontroller. The firmware cannot be modified or replaced by the user following its primary manufacturer installation.

Electromagnetic Compatibility

The Vcare α® must be connected to an external power adapter which meets the specifications listed in the specifications section of this manual. The maximal cable length between the adapter and the Vcare α® unit is 1.8 m.

The power adapter must be connected to a 3 pin certified power cable according to institute regulation. The maximal cable length should be 1.5 m.

Warning: Connecting the unit to power adapter and/or cable that don't meet the requirements listed above may result in increased emissions or decreased Immunity of the Vcare α® unit.

Guidance and Manufacturer Declaration – Electromagnetic Emissions		
The Vcare α® device is intended for use in the electromagnetic environment specified below. **The customer or the user of the Vcare α® device should assure that it is used in such an environment.**		
Emissions Tests	**Compliance**	**Electronic Environment – guidance**
RF emission CISPR 11	Group 1	The Vcare α® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	"The Vcare α® Device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes"
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Warning: the Vcare α® unit should not be used adjacent to or stacked with other equipment. In case such use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer Declaration – Electromagnetic Immunity

The Vcare α® device is intended for use in the electromagnetic environment specified below.

The customer or the user of the Vcare α® device should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance Level	Electronic Environment – guidance
Electromagnetic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	compliance	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	compliance	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	compliance	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dip, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) For 0,5 cycles 40% UT (60% dip in UT) For 5 cycles 70% UT (30% dip in UT) For 25 cycles <5% UT (>95% dip in UT) For 5 cycles	compliance	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Vcare α® requires continued operation during power mains interruptions, it is recommended that the Vcare α® be powered from an uninterruptable power supply or a battery.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	compliance	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer Declaration – Electromagnetic Immunity			
The Vcare α® device is intended for use in the electromagnetic environment specified below. The customer or the user of the Vcare α® device should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance Level**	**Electronic Environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of Vcare α® device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	$V_1 = 3V$	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P} = 1.16\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P} = 1.16\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P} = 2.33\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strength from fixed RF transmitter, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	$E_1 = 3V/m$	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection form structures, objects and people.

[a] Field strengths from fixed transmitters, such as base station for radio (cellular/cordless) telephones and mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electronic site survey should be considered. If the measured field strength in the location in which the Vcare α® device is used exceeds the applicable RF compliance level above, the Vcare α® device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Vcare α® device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

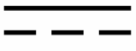
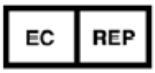
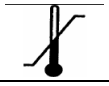
Recommended separation distances between portable and mobile RF communication equipment and the Vcare α® device

The Vcare α® device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.
The customer or the user of the Vcare α® device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Vcare α® device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of the transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
0.01	0.17	0.17	0.23
0.1	0.37	0.37	0.07
1	1.16	1.16	2.33
10	3.69	3.69	7.38
100	11.66	11.66	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter in watts (w) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection form structures, objects and people.

Definitions of symbols used

	Warning for possible hazard to system, patient or operator		Manufacturer
	Important Operational Information	SN	Serial Number
	Follow Instructions For Use	REF	Model Name
	Not for General Waste		Direct Current
	Fuse		Do not reuse
	Type BF Applied Part		Authorized Representative in the European Community.
	On		Do not re-sterilize
	Keep dry		Off
	Temperature Limits Symbol		This side up
	Manufactory date		Batch lot number
	Medical Equipment classified with respect to Electrical Shock, Fire and Mechanical Hazards		Model name
	Sterile unless the package is damaged or open		Caution
	Expiration date		Sterilized using irradiation
	Fragile		Recycle
	Marks portable and mobile RF communications equipment that may interfere in the vicinity of the device		Keep away from sunlight
	Certifies that a product has met European Union consumer safety, health or environmental requirements		Latex free

	Biohazard		

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